

## REMARKS

Applicant submits the present amendment after allowance to a) correct the record to reflect the title as amended by applicant's amendment mailed June 7, 2000; and b) correction of the PAIR "image file wrapper" to include a missing Letter of Suspension mailed August 12, 2003.

### Correction of the Title

The Notice of Allowance mailed August 10, 2007, incorrectly sets forth the title of the invention as "*Diagnosis of Retinoblastoma*". Applicant requests that the title of record be corrected.

In a Supplemental Preliminary Amendment filed on June 7, 2000, applicant amended the title to "*Retinoblastoma Nucleic Acids*". See, Supplemental Preliminary Amendment, June 7, 2000, at page 1 (attached as Exhibit A hereto.<sup>1</sup>) Confirmation that the Supplemental Preliminary Amendment was entered by the examiner is reflected in the statement of "Disposition of Claims" set forth in the Requirement for Restriction mailed December 18, 2000.

Correction of the title of record, to reflect the amendment to the title made in the Supplemental Preliminary Amendment mailed June 7, 2000, is respectfully requested.

### Correction of PAIR Image File Wrapper

Applicant requests that the PAIR "Image File Wrapper" be corrected to include the Letter of Suspension mailed August 12, 2003 (paper no. 22). A copy of the missing Letter of Suspension is attached as Exhibit B hereto.

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<sup>1</sup> Applicant notes that the record in private PAIR incorrectly identifies the June 7, 2000, Supplemental Preliminary Amendment as an "Amendment After Non-Final Rejection".

Applicant refers the examiner to the "Patent Term Extension History" tab of PAIR, which lists the Letter of Suspension of August 12, 2003. However, it is noted that the list of documents described at the "Image File Wrapper" tab is missing this document. The undersigned has downloaded and examined the full contents of the PAIR Image File Wrapper, and the document appears to be missing entirely from the electronic file wrapper.

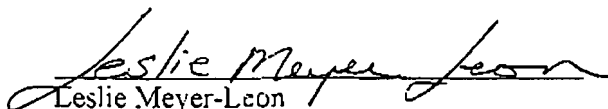
Accordingly, applicant respectfully requests that the PAIR record be corrected to include a copy of the Letter of Suspension dated August 12, 2003, as shown at Exhibit B.

CONCLUSION

Applicant submits that the application is in condition for allowance. Please charge any outstanding fees or credit any overpayments to Deposit Account No. 50-1895, Ref. No. 0300-005009.

Respectfully submitted:

Date: Sept 28, 2007

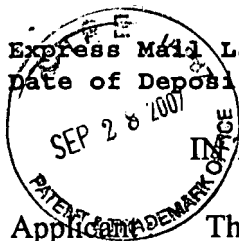
  
Leslie Meyer-Leon  
Reg. No. 37,381

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Enclosures:

Exhibit A (5 pgs.)  
Exhibit B (2 pgs.)  
Postcard

0300-005009/25764.doc



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thaddeus P. Dryja et al.

Art Unit:

Serial No.: 09/387,158

Examiner:

Filed: August 31, 1999

Title: DIAGNOSIS OF RETINOBLASTOMA

Assistant Commissioner of Patents and Trademarks  
Washington, DC 20231

SUPPLEMENTAL PRELIMINARY AMENDMENT

Prior to examination, please amend the application as follows:

In the Title:

In the title, replace "DIAGNOSIS OF RETINOBLASTOMA" with

- RETINOBLASTOMA NUCLEIC ACIDS -.

In the Claims:

Cancel claims 5, 17, 32-41, and 43-48. Amend claims 22, 24-27, 30-31, and 42. Add claims 49-52.

22. (Amended) A method of detecting a mutated retinoblastoma ("RB") nucleic acid in a mammal[s], the method comprising the steps of:

- (i) hybridizing an isolated full-length, wild-type RB cDNA probe to a [human] cell sample; and
- (ii) detecting a mutated RB nucleic acid.

23. A method of detecting a mutated retinoblastoma ("RB") gene in a human, the method

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Date of Deposit: June 7, 2000. I hereby certify under 37 C.F.R. § 1.10 that this correspondence is being deposited with the United Postal Services as "Express Mail Post Office to Addressee" with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231.

By: Mackali D. Berkowski

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comprising the steps of:

- (i) isolating RNA from a cell sample;
- (ii) hybridizing the RNA with an isolated full-length, wild-type RB cDNA probe; and
- (iii) detecting the presence of an abnormal RB RNA, the presence of a normal RB RNA or absence of an RB RNA, wherein the presence of an abnormal RB RNA or the absence of an RB RNA indicates a mutated RB gene.

24. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence encoding a full length human wild type retinoblastoma protein, as shown in exons 1-27, inclusive, in FIG. 6.

25. (Amended) The isolated nucleic acid molecule of claim 24, wherein the nucleotide sequence is as shown in exons 1-27, inclusive, in FIG. 6.

26. (Amended) An isolated nucleic acid molecule [comprising a nucleotide sequence] encoding [full-length] retinoblastoma protein.

27. (Amended) The nucleic acid molecule of claim 26, wherein said [full-length] retinoblastoma protein has the amino acid sequence encoded by [of] exons 1-27, inclusive, as shown in FIG. 6.

28. The nucleic acid molecule of claim 26, wherein said nucleic acid has an open-reading frame, and wherein the 5' end of said open-reading frame is shown at nucleotide position four of the nucleotide sequence shown in FIG. 5, and the 3' end of said open-reading frame is shown at nucleotide position 2784 of the nucleotide sequence shown in FIG. 5.

29. The nucleic acid molecule of claim 26, wherein said retinoblastoma protein is normal retinoblastoma protein.

30. (Amended) The [An isolated] nucleic acid molecule of claim 28, wherein said nucleic acid encodes [comprising a nucleotide sequence encoding a retinoblastoma protein, wherein said protein has] an amino acid sequence [as] shown in FIG. 5.

31. (Amended) A method of using a nucleic acid of any one of claims 24-30 to express a polypeptide encoded by said nucleic acid, said method comprising the steps of providing said nucleic acid in a cell or in an expression system, and expressing said polypeptide from said nucleic acid.

42. (Amended) The nucleic acid [polypeptide] of claim 26 [41], wherein said nucleic acid is [polypeptide is encoded by] an allelic variant of a human retinoblastoma gene.

49. (New) The method of claim 22, wherein said cell sample is a human cell sample.

50. (New) The nucleic acid of claim 28, wherein said nucleic acid encodes a polypeptide having an amino acid sequence predicted from said open-reading frame.

51. (New) The nucleic acid molecule of claim 26, wherein said nucleic acid has an open-reading frame, and wherein the 5' end of said open-reading frame is shown at nucleotide position 337 of the nucleotide sequence shown in FIG. 5, and the 3' end of said open-reading frame is shown at nucleotide position 2784 of the nucleotide sequence shown in FIG. 5.

52. (New) The nucleic acid molecule of claim 51, wherein said nucleic acid encodes a polypeptide having an amino acid sequence predicted from said open-reading frame.

#### REMARKS

The invention relates to retinoblastoma nucleic acids. Claims 5, 17, 32-41, and 43-48 are cancelled without prejudice.

Claims 22, 24-27, 30-31, and 42 are amended and claims 49-52 are added to more fully claim applicants' invention. The amendments to the claims are supported by the specification as

a whole and as follows: claims 24-27, 30 and 50-52 are supported, *inter alia*, by Figure 5 and by Figure 6. Claim 31 is supported, *inter alia*, by the specification of parent application U.S. Serial No. 06/895,163, filed August 11, 1986, at page 16, lines 9-15 ("The Rb protein is produced by cloning the Rb cDNA from p4.7R into an appropriate mammalian expression vector, expressing the Rb protein from this vector in an in vivo expression system, and isolating the Rb protein from the medium or cells of the expression system. General in vitro expression vectors and systems are well known in the art.").

### CONCLUSION

In view of the foregoing, it is submitted that the application is in condition for allowance and such action is respectfully requested. Please charge any fees or apply any credits to our Deposit Account No. 50-0311, Ref. No. 19100-021.

Respectfully submitted,

Date:

June 7, 2000



Leslie Meyer-Leon

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Approved for use through 03/31/2007. OMB 0851-0031

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 11

Application Number	09/387,158
Filing Date	August 31, 1999
First Named Inventor	Dryja et al.
Art Unit	1631
Examiner Name	Zeman, Mary K.
Attorney Docket Number	0300-005009

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input checked="" type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	Exhibit A (5 pgs.)
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	Exhibit B (2 pgs.)
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	Return Receipt Postcard
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	IP Legal Strategies Group P.C.		
Signature	<i>Leslie Meyer-Leon</i>		
Printed name	Leslie Meyer-Leon, Esq.		
Date	Sept 28, 2007	Reg No.	37,361

### CERTIFICATE OF TRANSMISSION/MAILING

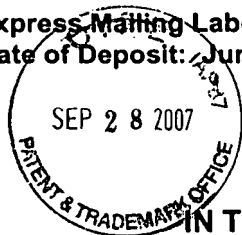
I hereby certify that this correspondence is being <del>transmitted</del> transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as <del>first class</del> mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: <u>Express Mail</u>			
Signature	<i>Karen A. Herrand</i>		
Typed or printed name	Karen A. Herrand By Express Mail No. EV644013049US	Date	Sept. 28, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form, and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**PATENT**  
**Attorney Docket No. 19100-021**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS : Thaddeus P. Dryja et al.  
SERIAL NUMBER : 09/387,158 EXAMINER : Not Yet Assigned  
FILING DATE : August 31, 1999 ART UNIT : Not Yet Assigned  
FOR : DIAGNOSIS OF RETINOBLASTOMA

June 7, 2000  
Boston, Massachusetts

Assistant Commissioner for Patents  
Washington, D.C. 20231

**TRANSMITTAL LETTER**

Transmitted herewith for filing in the present application are the following documents:

- ☒ Supplemental Preliminary Amendment
- ☒ Return Postcard

The Commissioner is authorized to credit any overpayment or charge any deficiencies to Deposit Account No. 50-0311, Reference No. 19100-021. A duplicate copy of this Transmittal Letter is enclosed.

If the enclosed papers are considered incomplete, the Mail Room is respectfully requested to contact the undersigned collect at (617) 542-6000, Boston, Massachusetts.

Respectfully submitted,

A handwritten signature in cursive script, reading "Leslie Meyer-Leon".

Leslie Meyer-Leon, Reg. No. 37,381  
Attorney for Applicants  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/387,158	08/31/1999	THADDEUS P. DRYJA	19100-021	2246

32665 7590 08/12/2003

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IP LEGAL STRATEGIES

EXAMINER

ZEMAN, MARY K

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 08/12/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED  
Action Due status check  
Docket Date 2/11/04  
Initials XC 8/18/03



UNITED STATES  
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Paper No: 22

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CENTERVILLE MA 02632-1210

Re: 09/387,158

All claims are allowable. However, due to a potential interference, *ex parte* prosecution is suspended for a period of six (6) months.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K. Zeman whose telephone number is (703) 305-7133.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael P. Woodward  
SPE AU 1631  
Technology Center 1600

John Doll  
Director  
Technology Center 1600

August 11, 2003